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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 91N–0278]

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to correct certain errors that were incorporated into the regulations. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has discovered certain errors that were inadvertently included in the agency's codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of December 11, 1992 (57 FR 58942), we published a final rule that, among other things, established subpart E of part 601, which encompasses §§ 601.40 through 601.46. Currently, § 601.43(a) refers to § 601.40, instead of the correct § 601.41; § 601.43(b) refers to § 601.40, instead of the correct § 601.42. Accordingly, we are amending § 601.43(a) by replacing the incorrect reference to § 601.40 with a reference to § 601.41, and we are amending § 601.43(b) by replacing the incorrect reference to § 601.40

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with a reference to § 601.42. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356B, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.43 [Amended]

■ 2. Section 601.43 *Withdrawal procedures* is amended in the introductory text of paragraph (a) by removing "§§ 601.40 and 640.42" and adding in its place "§ 601.41 or § 601.42", and in paragraph (b) by removing "§ 601.40 or § 601.41" and adding in its place "§ 601.41 or § 601.42".

Dated: 6/4/03
June 4, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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